MAR 4 - 2005

K050175

Spacelabs Medical, Inc. Special 510(k)
Multiparameter Module 91496 with Option N
510(k) Summary

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 1992.

Date:	January, 2005
Submitter:	Spacelabs Medical, Inc. 5150 220th Avenue SE Issaquah, WA 98029 Mr. Al Van Houdt 1 425 657 7200, x5970 1 425 657 7210 (FAX) Al.VanHoudt@slmd.com
Proprietary Name:	Spacelabs Medical Multiparameter Module 91496 (Option N)
Common Name and Classification:	Arrhythmia Detector and Alarm 74DSI, §870.1025, Class II Noninvasive Blood Pressure Measurement System 74DXN, §870.1130, Class II Oximeter 74DQA, §870.2700, Class II Blood Pressure Computer 74DSK, §870.1110, Class II Clinical Electronic Thermometer 80BWX, §880.2910, Class II Thermal Cardiac Output Monitor 74KFN, §870.1435, Class II
Predicate Devices:	K972502: Spacelabs Medical Integrated Multiparameter Module 90496 K012891: OxiMAX Pulse Oximetry System with N-595 Pulse Oximeter and OxiMAX Sensors and Cables

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Multiparameter Module 91496 with Option N
510(k) Summary

Device Description:	The Spacelabs Medical Multiparameter Module 91496 with Option N is a slim, lightweight singular modular unit that, when used in conjunction with a Spacelabs Medical Patient Care Management System (PCMS), provides the capability to acquire various common physiologic data in a clinical setting. The Module 91496 is the primary interface to the patient being monitored. The Module 91496 is capable of acquiring and processing ECG, respiration, invasive and noninvasive blood pressure, temperature, cardiac output and SpO_2 parameters for a single patient. The Module 91496 accumulates the patient physiological data of interest and provides both waveform and digital data to a Spacelabs Medical PCMS monitor via SDLC communications. The PCMS monitor will provide the display capabilities for the care provider. Option N utilizes Nellcor Puritan Bennett OxiMax oximetry and sensors and OxiMax-compatible adapter cables.
Intended Use:	The Spacelabs Medical Multiparameter Module 91496 is intended for use with the PCMS to acquire, monitor and process various clinical parameters from adult or neonatal/infant populations in any type of clinical environment other than home use. Physiologic parameters that may be monitored include cardiac activity, respiration, invasive and noninvasive blood pressure, temperature, oxygen saturation (SpO2), and cardiac output. Acquired data may then be communicated to an information network for display, recording, editing and analysis.
Comparison of Technological Characteristics:	The Spacelabs Medical Multiparameter Module 91496 with Option N is substantially equivalent to the Spacelabs Medical Multiparameter Module 90496 in design concepts, technologies, materials and intended use, and to the Nellcor N-595 Pulse Oximeter with regard to SpO2 analysis.
Test Discussion:	The Module 91496 was validated through rigorous testing that, in part, support the compliance of the Module 91496 to applicable standards. Additionally, the software for the Module 91496 was developed following a robust software development process and was fully specified and validated. Safety testing has been performed by third party agencies to ensure the device complies with applicable industry and safety standards.
Testing Conclusion:	The Module 91496 is substantially equivalent to its predicate devices in design concepts, technologies, materials and intended use.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 4 - 2005

Mr. Al Van Houdt
Director, Regulatory Affairs and Quality
Spacelabs Medical, Incorporated
5150 220th Avenue SE
Issaquah, Washington 98027

Re: K050175
Trade/Device Name: Spacelabs Medical Multiparameter Module 91496 with Option N
Regulation Number: 870.2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA, DSI, LOS, DXN, DSK, DXG, FLL
Dated: February 24, 2005
Received: February 25, 2005

Dear Mr. Houdt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050175

Device Name: Spacelabs Medical Multiparameter Module 91496 with Option N

Indications for Use:

Conditions to be screened, monitored, treated or diagnosed.

Patient conditions indicated by abnormalities in various physiologic parameters, including ECG waveform, respiratory effort, invasive and noninvasive blood pressure measurements, temperature, cardiac output, and pulse oximeter (SpO_2) readings.

Prescription use only.

Yes. Caution statement is provided in the introductory page of the Patient Care Management System which includes the operating instructions for this Module.

Parts of body applied to.

Specific to the physiologic parameter being monitored, accessories may be applied externally to the chest and limbs or invasively into the blood stream.

Frequency of use.

Frequency as directed by physician.

Physiological purpose.

In conjunction with clinical findings, a screening and diagnostic tool for use in:

- assessing electrical activity of the heart in order to detect abnormal cardiac rhythms, including life threatening events such as high and low heart rates, asystole and ventricular fibrillation as well as, in adults, the detection of rhythms such as ventricular runs, tachycardia, and ST segment deviations;
- monitoring respiratory effort to detect abnormal respiration events such as high and low respiration rates and episodes of apnea;
- continuous monitoring of invasive pressure signals to detect abnormal events such as high and low pressure;
- episodic monitoring of noninvasive pressure signals to detect abnormal events such as high and low pressure;
- continuous monitoring of temperature signals to detect abnormal events such as high and low body temperature;
- monitoring of the patient's pumping ability of the heart and various hemodynamic values to detect abnormal flow volumes; and
- noninvasive, continuous monitoring of pulse oxygen saturation signals in order to detect desaturation due to abnormal pulmonary/circulatory functions.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off) Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number K050175